DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

Biomet Spine
Mr. Ted Kuhn
Regulatory Affairs Product Manager
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K141791
Trade/Device Name: Biomet Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX, ODP, MQP
Dated: September 9, 2014
Received: September 11, 2014

Dear Mr. Kuhn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141791

Device Name
Biomet Fusion System

Indications for Use *(Describe)*
When used as a cervical intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Biomet Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.

When used as a lumbar intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants with 20 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least one integrated fixation screw. The Biomet Fusion System is to be combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Biomet Spinal Fixation System. The Biomet SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplement fixation.

When used as vertebral body replacement, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Biomet Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e. T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Biomet Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Biomet Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	September 30, 2014
Applicant/Sponsor:	Biomet Spine 310Interlocken Parkway, Suite 120 Broomfield, CO 80021
Contact Person:	Ted Kuhn Regulatory Affairs Project Manager Phone: 303-501-8549 Fax: 303-501-8444
Trade name:	Biomet Fusion System
Common Name:	Intervertebral fusion device with bone graft, cervical; Intervertebral fusion device with bone graft, lumbar; Intervertebral Body Fusion Device with Integrated Fixation, Lumbar; Vertebral Body Replacement
Classification Name	Orthosis, spinal intervertebral fusion and/or Spinal intervertebral body fixation orthosis.
(Product Code):	(ODP, MAX, OVD, MQP)
Device Panel - Regulation No.:	Orthopedic - 21 CFR § 888.3080 and/or § 888.3060

Device Description:

Biomet Fusion System implants consist of a spacer body with screws for additional fixation. The Biomet Fusion System the spacer body is made from PEEK-OPTIMA® LT1, a polyaromatic semicrystalline thermoplastic polymer (-C_6H_4-O-C_6H_4-O-C_6H_4-CO-). The Biomet Fusion System implants include an anterior plate and screws made from an implant grade titanium alloy (Ti-6Al-4V ELI) meeting the requirements of ASTM F136-08 and ISO 5832-3. The spacer body, plates and screws are available in a variety of sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Biomet Fusion System is provided non-sterile.

The implants included in this application are intended for us in lumbar intervertebral body fusion. The implants have a hollowed out central area to accommodate bone graft. The upper and lower surfaces of each implant have a series of transverse grooves formed to improve stability and fixation once the device is inserted.

The purpose of this 510(k) Notification is to seek clearance for a modification to the Lanx Fusion System, for additional configurations. The new implants are also referred to as the Biomet Fusion System.

Indications for Use:

When used as a cervical intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Biomet Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Anterior Cervical Plate System.

When used as a lumbar intervertebral body fusion device, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants with 20 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least one integrated fixation screw. The Biomet Fusion System is to be combined with supplemental fixation (except as noted below). Approved supplemental fixation systems include the Biomet Spinal Fixation System. The Biomet SA standalone interbody implants, when implanted via an anterior approach and used with the integrated fixation screws, do not require use of supplement fixation.

When used as vertebral body replacement, the Biomet Intervertebral Body/VBR Fusion System ("Biomet Fusion System") is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) The Biomet Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e. T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Biomet Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Biomet Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

Summary of Technologies:

This submission is intended to seek clearance for a product line extension to the Biomet Fusion System. The product line extension includes new configurations of a PEEK spacer body similar to the existing PEEK spacer body of the previously cleared Biomet Fusion System.

All components in the Biomet Fusion System are made of PEEK (OPTIMA®) per ASTM F2026 and Titanium alloy (Ti-6Al-4V) per ASTM F136. The PEEK components include Tantalum markers per ASTM F560. The Biomet Fusion System has a hollowed out area to accommodate autogenous bone graft, and transverse grooves to improve fixation and stability. It is available in a variety of different sizes to accommodate anatomical variation in different vertebral levels and/or patient anatomy. It

comes available with plates and screws to provide additional fixation; however, these are intended to be used with supplemental fixation. The Biomet Fusion System is provided non-sterile.

The additional devices added to the product line have the same or similar intended use and indications, principles of operation, and technological characteristics as the current Biomet Fusion System. The minor differences between the current devices and the devices added to the product line do not raise any new questions of safety or effectiveness. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate device.

Performance Data:

Performance testing performed to demonstrate substantial equivalence:

- Static Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Dynamic Compression per ASTM F2077
- Expulsion Testing per ASTM Draft Z8423Z
- Cadaveric Study

In all instances, the Biomet Fusion System met acceptance criteria and functioned as intended.

Substantial Equivalence:

The additional devices included in the product line extension have the same or similar intended uses, indications, technological characteristics, and principles of operation as previously cleared primary predicate Lanx Fusion System (K131547). Performance data demonstrate that these additions to the Biomet Fusion System do not raise new issues of safety or effectiveness; hence it is as safe and effective as its predicate devices. Thus, the additional devices are substantially equivalent.

Conclusion:

In summary, the modified Biomet Fusion System has the same or similar: intended use, indications for use, technological characteristics, principles of operation and performances as the previously cleared primary predicate Lanx Fusion System (K131547) and (K123767). Performance testing demonstrates that the modified implants are stronger than or as strong as the predicate implants and provide equivalent performance. Thus, the addition of the new implant models do not raise new questions of safety and efficacy and is substantially equivalent to previous cleared primary predicate Lanx Fusion System (K131547) and K123767).